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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,819	01/15/2004	Fred J. Molz IV	MSDI-667/PC860.00	5404
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EXAMINER				
BLANCO, JAVIER G				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,819

Applicant(s)

MOLZ, FRED J.

Examiner

JAVIER G. BLANCO

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8, 10-16, 18-24, 27-33, 63, 65-71, 74-78, 80, 81 and 89-97 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 6-8, 10-15, 18-24, 27-33, 63, 65-71, 74-78, 80, 81 and 89-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 3-6, 15, 18, 27-30, 32, , 33, 63, 65, 70, 71, 74-78, 80, 81, and 89 in the reply filed on September 25, 2008 is acknowledged.
2. Applicant's cancellation of claims 9, 17, 34, 64, 73, 82-85, 87, and 88 in the reply filed on September 25, 2008 is acknowledged.
3. Applicant's addition of claims 91-97 in the reply filed on September 25, 2008 is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 3, 6-8, 10-15, 19, 21-24, 27-33, 63, 66-71, 74-78, 80, 81, and 89-97 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Michelson** (US 6,120,503 A).

Referring to Figures 29-32 and 33-35, Michelson discloses a spinal construct comprising:

- a. A rectangular (see column 15, lines 19-21) spinal implant (Figures 29-32: spinal implant 540, having openings 542, 544; Figure 33: spinal fusion implant 610, having through-openings) comprising an intervertebral fusion device including a hollow interior with openings in

communication with said hollow interior (Figure 33: interior chamber 614; see claim 1); said device extending along a longitudinal axis and including a first pair of side surfaces (e.g., opposite sides of circumferential groove) spaced apart and arranged generally opposite one another to define a first transverse dimension sized for insertion within an intervertebral space between the adjacent vertebral bodies; and a second pair of side surfaces (e.g., opposite sides of thread/ridge) spaced apart and arranged generally opposite one another to define a second transverse dimension greater than said first transverse dimension and corresponding to a select height of said intervertebral space (e.g., when rotating or screwing the spinal fusion implant into the disc space, the thread/ridge will distract the disc space);

b. A bone growth promoting material positioned within said hollow interior (see Figure 33; see claim 1); and

c. An elongate member (Figures 29-32: plate member 512; Figure 33: plate member 510; Figure 35: plate member 710) sized to span the intervertebral space and a plurality of bone anchors extending transversely from said elongate member (Figures 29-32: bone anchors 516, 517; Figure 33: bone anchors 516, 517; Figure 35: screws 716, 717), wherein said spinal implant is rotatably coupled (Figures 29-32: knobs 532, 534 and/or screw 50; Figure 33: threaded post 622; Figure 35: central opening 18 receives screw 60) with said elongate member. As clearly shown in the Figures, said device includes a rounded transitional surface at diagonally opposite corner portions extending between said first pair of side surfaces and said second pair of side surfaces. Regarding the interlock (see claims 10-12 and claims 30-31), see Figures 25, 26, 30, and 35, clearly showing posts (e.g., tabs/knobs 532, 534) received in complementary apertures; threaded post 622 and threaded aperture 620; and coupling means 18 (aperture, which could be threaded)

and 60 (screw). The at least one projection and the at least one aperture are each offset from the implant longitudinal axis. Regarding the at least two tool engaging elements on the spinal implant, see rectangular projections on basal face of implant. The elongate member defines a pair of arcuate slots positioned diametrically opposite one another relative to the longitudinal axis (see Figures 29-32 and 35).

With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Michelson**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

6. Claims 3, 6-8, 10-12, 19, 23, 24, 27-33, 63, 66-71, 74-78, 80, 81, and 89-97 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Benezech et al.** (US 6,235,059 B1). Referring to Figures 1-3 (particularly Figure 1), Benezech et al. disclose a spinal construct comprising:

a. A parallelepiped (see column 1, lines 61-63; column 2, lines 19-21) spinal implant comprising an intervertebral fusion device (cage 1) having a substantially rectangular transverse cross section and including a hollow interior with openings in communication with said hollow interior (clearly seen in Figures; see column 2, lines 35-37); said device extending along a longitudinal axis and including a first pair of side surfaces (8, 9) spaced apart and arranged generally opposite one another to define a first transverse dimension; and a second pair of side surfaces (2, 4) spaced apart and arranged generally opposite one another to define a second transverse dimension greater than said first transverse dimension;

b. A bone growth promoting material positioned within said hollow interior (see column 1, lines 61-65; column 3, lines 3-5); and

c. An elongate member (plate 12) sized to span the intervertebral space and a plurality of bone anchors extending transversely from said elongate member (see column 2, lines 40-45; column 3, lines 34-44). Said spinal implant is rotatably coupled with said elongate member: cage 1 comprises cylindrical stud 15, which stud 15 comprises a peripheral groove 17. Cylindrical stud 15 rotatably engages, due mostly in part by peripheral groove 17, enlarged portion 18 of oblong slot 19 of plate 12. The fusion device may have any of several transverse cross-sections (e.g., rectangular, circular, ovoid; etc.), as taught in column 2, lines 65-67. As clearly shown in the Figures, said device includes a rounded transitional surface at diagonally opposite corner portions (see corners) extending between said first pair of side surfaces and said second pair of side surfaces. The interlock will be the end 20 of slot 19, and attachment of plate 12 to adjacent vertebrae. Regarding claim 19, see corners of cage 1. It should be noted Benzezech et al. disclose plate 12 could be monolithic with cage 1, OR modular with cage 1 (see column 2, lines 43-51).

With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Benezech et al.**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

7. Claims 3, 6-12, 15, 19-21, 23, 24, 27-32, 63, 64, 66-71, 73-76, 78-80, 82-85, 87, 89, and 91-96 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Kohrs** (US 6,224,631 B1).

Referring to Figures 1-20, Kohrs discloses a spinal implant assembly, comprising:

a. A device comprising a fusion cage (10) *adapted for insertion* into an intervertebral space between an adjacent pair of vertebral bodies, said device extending along a longitudinal axis and defining a primary transverse dimension and a secondary transverse dimension, said secondary transverse dimension *sized for insertion* into the intervertebral space, said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space, wherein the fusion cage further comprises rounded

transitional surfaces and apertures (tool engaging elements) to receive projection portions (see **representation of Figure 17 of Kohrs '631, below**);

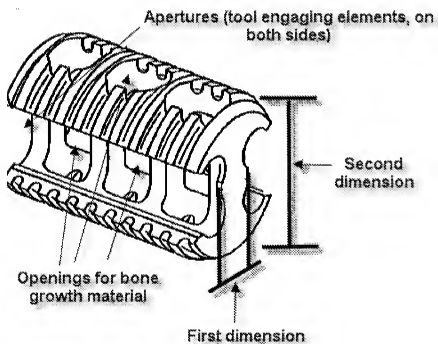
b. A bone growth promoting material (e.g., bone growth matrix) positioned within said fusion cage to facilitate fusion with the adjacent vertebral bodies; and

c. An elongate member (Figure 17: elongate member 500, comprises a plurality of bone anchors 526, 527 and plate-shaped projection/interlock 506 comprising projection portions 523, 524) *sized to span* the intervertebral space and a plurality of bone anchors (526, 527) extending transversely from said elongate member and into engagement with the adjacent vertebral bodies. As seen in Figure 17, said spinal implant is engaged with said elongate member *to allow* selective rotation of said spinal implant relative to said elongate member about said longitudinal axis, said selective rotation of said spinal implant *serving to transition* said first transverse dimension to said second transverse dimension along said select height of the intervertebral space.

Regarding the limitation/closure “*to establish* said select height of the intervertebral space and *to maintain* said select height as said device is rotated/transitioned (e.g., the device is rotated, screwed, and/or manipulated during surgery) about said longitudinal axis *to align* said primary transverse dimension along said select height *to thereby provide* controlled compression of said device”, (i) it does not provide structure to the spinal construct, and (ii) it does not provide structural relationship between the fusion device and the “elongate member”.

With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide*; etc.), they do not impose any structural limitations on the claims distinguishable over the device of Kohrs,

which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danyl*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).



8. Claims 3, 8-12, 18, 24, 28-32, 34, 63-71, 73-85, and 87-90 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Bonutti** (US 6,099,531 A).

Referring to Figures 10, 14-16, and 24, Bonutti discloses a spinal implant assembly (see column 2, lines 25-34), comprising:

- a. A device comprising a porous fusion cage 44 (see columns 10, 11: "hollow wedge member") *adapted for insertion* into an intervertebral space between an adjacent pair of vertebral bodies (see column 2, lines 25-34), said device extending along a longitudinal axis and defining a primary transverse dimension and a secondary transverse dimension, said secondary transverse dimension *sized for insertion* into the intervertebral space, said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space (clearly seen in Figures 14 and 15);
- b. A bone growth promoting material (110) positioned within said fusion cage to facilitate fusion with the adjacent vertebral bodies (see columns 10, 11: "hollow wedge member"), wherein said bone growth promoting material comprises a bone morphogenic protein (see column 10, lines 9-24); and
- c. A plate (Figure 16: end portion 50d) having first (144) and second (146) end portions and a plurality of bone screws (70, 72) extending transversely from said plate. As seen in Figures 14-16, said spinal implant is engaged with said elongate member *to allow* selective rotation of said spinal implant relative to said elongate member about said longitudinal axis, said selective rotation of said spinal implant *serving to transition* said first transverse dimension to said second transverse dimension along said select height of the intervertebral space. Alternatively, the "elongate member" could be broadly interpreted as the combination of end portion 50b/ 60b (Figure 10) and the elongated tool engaging said end portion, and the "bone anchor" could be broadly interpreted as either bone screws 70, 72 and/or frictional forces between the implant, the

"elongate member", and the vertebral surfaces. The "interlock" as claimed could be broadly interpreted as aperture 140 receiving a manipulation tool, and/or the frictional forces between the implant, the "elongate member", and the vertebral surfaces.

Regarding the limitation/closure "to establish said select height of the intervertebral space and to maintain said select height as said device is rotated/transitioned (e.g., the device is rotated, screwed, and/or manipulated during surgery) about said longitudinal axis to align said primary transverse dimension along said select height to thereby provide controlled compression of said device", (i) it does not provide structure to the spinal construct, and (ii) it does not provide structural relationship between the fusion device and the "elongate member".

With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide*; etc.), they do not impose any structural limitations on the claims distinguishable over the device of **Bonutti**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 6-8, 10, 11, 18, 19, 23, 24, 27-33, 63, 65-71, 74-78, 80, 81, and 89-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Beckers et al.** (US 5,888,224 A) in view of **Benezech et al.** (US 6,235,059 B1).

Referring to Figures 3-14, **Beckers et al.** disclose a spinal construct comprising:

- a. A rectangular (see column 5, lines 22-24) implant comprising an intervertebral fusion device (fusion cage 6) having a parallelepiped configuration (see Figures) and including a hollow interior with openings in communication with said hollow interior (see Figures 3 and 15; see column 4, lines 11-18; column 7, lines 13-22); said device extending along a longitudinal axis (35) and including a first pair of side surfaces (e.g., opposite sides 14, 15; see Figures 10-13) spaced apart and arranged generally opposite one another to define a first transverse dimension sized for insertion within an intervertebral space between the adjacent vertebral bodies; and a second pair of side surfaces (e.g., opposite sides 16, 17; see Figures 10-13) spaced apart and arranged generally opposite one another to define a second transverse dimension greater than said first transverse dimension and corresponding to a select height of said intervertebral space (25);
- b. A bone growth promoting material positioned within said hollow interior (material 24; see column 4, lines 11-18; column 7, lines 13-22); and

c. An elongate member (Figures 13 and 14: plate 34) sized to span the intervertebral space, wherein said spinal implant is rotatably coupled with said elongate member, and rotate about its longitudinal axis while rotatably coupled to said elongate member (see Figure 14; see column 7, lines 1-12). As clearly shown in the Figures, said device includes a rounded transitional surface at diagonally opposite corner portions extending between said first pair of side surfaces and said second pair of side surfaces (e.g., rounded sides 31, 32; see column 6, lines 37-45). Once the cage is in its final position, it will be interlocked to plate 34.

With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Beckers et al.**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Regarding the bone growth promoting material as comprising a bone morphogenic protein, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used bone morphogenic protein as the bone growth promoting material of **Beckers et al.**, since it has been held to be within the general skill of a worker in the

art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Beckers et al. did not particularly disclose plate 34 as defining a first opening overlapping one of the adjacent vertebral bodies and a second opening overlapping another of the adjacent vertebral bodies, and a plurality of bone anchors extending transversely from said plate. However, this is already known in the art. For example, **Benezech et al.** teaches a plate defining a first opening overlapping one of the adjacent vertebral bodies and a second opening overlapping another of the adjacent vertebral bodies, and a plurality of bone anchors extending transversely from said plate (see 102(b) rejection, above) in order to rotatably couple to a fusion cage during insertion, manipulation, and/or rotation of said cage, and to subsequently assist said cage with maintaining a selected height of a disc space while maintaining the cage securely in place. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a plate defining a first opening overlapping one of the adjacent vertebral bodies and a second opening overlapping another of the adjacent vertebral bodies, and a plurality of bone anchors extending transversely from said plate, as taught by **Benezech et al.**, with the invention of **Beckers et al.**, in order to rotatably couple to a fusion cage during insertion, manipulation, and/or rotation of said cage, and to subsequently assist said cage with maintaining a selected height of a disc space while maintaining the cage securely in place.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would

improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Response to Arguments

11. Regarding the 102(b) rejection based on **Kohrs** (US 6,224,631 B1), Applicant's arguments filed September 25, 2008 have been fully considered but they are not persuasive.

a. Regarding claim 27, the Applicant argues Kohrs '631 does not disclose his fusion cage/device as "wherein said device has a substantially rectangular transverse cross section". The Examiner respectfully disagrees. As part of the different embodiments, Kohrs teaches a fusion cage "wherein said device has a substantially rectangular transverse cross section" (see Figure 8).

b. Regarding claims 32, 63, 76, and 80, contrary to Applicant's opinion the Office Action set forth grounds as to how the implant of Kohrs could be construed as being "rotatably coupled" with the insertion tool. The tool, particularly its end, is "rotatably coupled" to the fusion cage. Rotation of the tool will cause rotation of the device. The language is broad enough to be interpreted this way.

c. It is noted Applicant's arguments are mostly based on statements of intended use and other functional statements. With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Kohrs**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

12. Regarding the 102(b) rejection based on **Bonutti** (US 6,099,531 A), Applicant's arguments filed September 25, 2008 have been fully considered but they are not persuasive.

a. Regarding each of claims 32, 63, 76, and 80, the Applicant argues Bonuti '531 does not disclose the fusion cage as "rotatably coupled" to the elongate member. The previous Office Action clearly show two alternative interpretations on how the fusion cage is "rotatably coupled" to the "elongate member". Regarding the functional limitation "to allow selective rotation of said spinal implant relative to said elongate member", the device of Bonutti has the same structure and is therefore capable of performing the function as claimed.

b. It is noted Applicant's arguments are mostly based on statements of intended use and other functional statements. With regards to statements of intended use and other functional statements (e.g., *for engagement; to define; sized for insertion; sized to span; to establish; to allow; to thereby provide; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Bonutti**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

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Primary Examiner, Art Unit 3738